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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,261	01/23/2004	Edward P. Perez	7404-612	6175

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EXAMINER

MARMOR II, CHARLES ALAN

ART UNIT	PAPER NUMBER
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3736

DATE MAILED: 08/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/764,261

Applicant(s)

PEREZ ET AL.

Examiner

Charles A. Marmor, II

Art Unit

3736

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is responsive to the Response to Restriction Requirement filed May 26, 2005.

Election/Restrictions

2. Applicant's election without traverse of Group I, claims 21-36, in the reply filed on May 26, 2005 is acknowledged. The Examiner further acknowledges the cancellation of claims 37-44. Claims 21-36 are pending.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 28, 32 and 36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear whether the "step for forming the incision in the tissue" is the same step of "forming an incision in tissue with a device" recited in the respective independent claims or if this step is a separate and distinct method step. Moreover, it is unclear whether the "step for expressing the body fluid" is the same step of "expressing body fluid" recited in the respective independent claims or if this step is a separate and distinct method step. If these steps are essentially same, it is unclear how these claims further limit the methods of the

Art Unit: 3736

respective independent claims. In this office action, the Examiner is interpreting these method steps to be the same step.

Claim Rejections - 35 USC § 102 and 35 USC § 103

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. The Examiner notes that the present application is a continuation of U.S. Application No. 09/879,991 filed June 14, 2001 which is a continuation-in-part of U.S. Application No. 09/542,040 filed March 31, 2000 which is a continuation of U.S. Application No. 09/285,021 filed June April 1, 1999 which is a continuation of U.S. Application No. 08/975,978 filed November 21, 1997. The Examiner notes that the first disclosure of the steps of “expressing body fluid from an incision by heating;” “expressing body fluid from an incision by applying ultrasound;” “expressing body fluid from an incision by depressing the tissue surrounding the

Art Unit: 3736

incision progressively closer to the incision” in the recited chain of continuity occurs in U.S.

Application No. 09/879,991, making the earliest effective filing date for this step June 14, 2001.

8. Claims 21-24, 26-28, 33 and 36 are rejected under 35 U.S.C. 102(b) as being anticipated by Cunningham et al. ('039). Cunningham et al. teach a method that includes the steps of forming an incision in tissue with a lancing mechanism on a device and expressing body fluid from the incision with the device. The step of expressing body fluid includes heating the tissue and applying a force to depress the tissue surrounding the incision using a skin stretching mechanism (see at least column 5, lines 35-54), where the force is applied in a direction inclined generally toward the incision (see at least Figures 2 and 4). The method may be performed at a location other than a fingertip (see at least column 10, lines 13-14). The step of expressing body fluid includes pinching the skin (see at least column 5, lines 48-51) which is consistent with depressing the tissue surrounding the incision progressively closer to the incision.

9. Claims 29 and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Eppstein ('434). Eppstein teaches a method that includes the steps of forming an incision in tissue with a device (80) and expressing body fluid from the incision with the device. The step of expressing body fluid includes applying ultrasound to a region of the incision using an ultrasonic system (104) on the device.

10. Claims 21-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Douglas et al. ('493). Douglas et al. teach a method that includes the steps of forming an incision in tissue with

Art Unit: 3736

a lancing mechanism on a device and expressing body fluid from the incision with the device.

The step of expressing body fluid includes at least one of heating the tissue, applying ultrasound to the region of the incision, and applying a force to depress the tissue surrounding the incision progressively closer to the incision.

11. Claims 21, 22, 27 and 28 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Douglas et al. ('210). Douglas et al. teach an apparatus and method for expressing body fluid from an incision where an incision is formed in tissue with a lancing mechanism on a device and body fluid is expressed from the incision with the device by heating the tissue in the region of the incision.

12. Claims 21, 22, 27-30 and 32 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Douglas et al. ('250). Douglas et al. teach an apparatus and method for expressing body fluid from an incision where an incision is formed in tissue with a lancing mechanism on a device and body fluid is expressed from the incision with the device by heating the tissue in the region of the incision or by applying ultrasound to the region of the incision.

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 25, 30 and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cunningham et al. ('039) in view of Eppstein ('434).

Cunningham teaches all of the limitations of the method of claim 25 except that the expressing includes applying ultrasonic frequency to the region of the incision. Eppstein teaches a method including such a method step, as discussed above. It would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use a step of applying ultrasonic frequency to a region of the incision similar to that of Eppstein as part of a method similar to that of Cunningham et al. in order to further enhance the expression of body fluids from the incision by increasing the permeability of the skin.

Eppstein teaches all of the limitations of the method of claims 30 and 31 except that the expressing includes applying a force to depress the tissue surrounding the incision such that the force is applied progressively closer to the incision. Cunningham et al. teach a method including such method steps, as discussed above. It would have been obvious to one having ordinary skill in the art at the time of Applicant's invention to use a step of applying a force to depress the tissue surrounding the incision such that the force is applied progressively closer to the incision similar to that of Cunningham et al. as part of a method similar to that of Eppstein in order to further enhance the expression of body fluids from the incision by compounding the means for expression.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible

Art Unit: 3736

harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 21-33, 35 and 36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 25 and 27-31 of U.S. Patent No. 6,706,000. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are merely broader than those of the patent. Claim 25 of the patent recites all the method steps of claims 33 and 36 of instant application, and several additional limitations not required by the claims of the instant application. Claims 27-31 of the patent recite all the method steps of claims 21-32 of instant application, and several additional limitations not required by the claims of the instant application. Claims 1 and 10 of the patent recite an apparatus that would inherently require the method steps of claims 33 and 35 of the instant application in order to operate. Since the aforementioned claims of the patent "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

17. Claims 21-36 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-8, 13, 17, 18, 20 and 21 of U.S. Patent No. 5,951,493. Although the conflicting claims are not identical, they are not patentably distinct

Art Unit: 3736

from each other because the claims of the instant application are merely broader than those of the patent. Claims 1-7 of the patent recite all the method steps of claims 21-33 and 36 of instant application, and several additional limitations not required by the claims of the instant application. Claims 8, 13, 17, 18, 20 and 21 of the patent recite an apparatus that would inherently require the method steps of claims 21-36 of the instant application in order to operate. Since the aforementioned claims of the patent "anticipate" the broader claims of the instant application, the claims are not patentably distinct.

18. Claims 21, 22, 27 and 28 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,319,210. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claim of the patent recites an apparatus that inherently would require all of the method steps of the aforementioned claims of the instant application in order to be operable.

19. Claims 21, 22, 27-30 and 32 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9 and 11 of U.S. Patent No. 6,071,250. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the patent recite apparatus that inherently would require all of the method steps of the aforementioned claims of the instant application in order to be operable.

Response to Arguments

20. Applicant's arguments with respect to claims 21-36 filed February 17, 2005 have been considered but are moot in view of the new ground(s) of rejection. Applicant remarked that independent claim 21 was added to vary the scope of protection for the features recited in canceled dependent claim 5 that was previously only rejected based on obviousness type double patenting rejections. Applicant further stated that independent claim 29 was added to vary the scope of protection for the features recited in canceled dependent claim 6 that was previously only rejected based on obviousness type double patenting rejections. Finally, Applicant argues that Lange ('166) does not teach or fairly suggest a method as recited in independent claim 33. These arguments are moot in view of the new grounds of rejection set forth hereinabove.

Conclusion

21. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

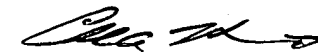
Art Unit: 3736

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

22. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charles A. Marmor, II whose telephone number is (571) 272-4730. The examiner can normally be reached on M-TH (7:00-5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Charles A. Marmor, II
Primary Examiner
Art Unit 3736

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August 10, 2005